Transcript

Fourth Meeting of the Secretary's Advisory Committee on Xenotransplantation, U.S. Department of Health and Human Services

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Breakout Session: SACX Working Group on the State of the Science in Xenotransplantation

Holiday Inn Select
8210 Wisconsin Avenue
Bethesda, Maryland 20814

Reported By:

L.A.D. Reporting Company
1684 East Gude Drive, Suite 201
Rockville, Maryland 20850
(301) 762-8282

P R O C E E D I N G S 10:20 A.M.

DR. SYKES: Okay. Well, let me just start by briefly stating what Jon and I were hoping we could accomplish during this breakout session. One is we've discussed this letter regarding xeno tourism, and we've been asked as a subcommittee to draft a letter, so I thought we could actually put that down on computer right now. I brought a laptop for that purpose. And secondly, we should follow up now on our last -- or I guess two meetings ago we broke out as a group, and we sort of outlined what the major sections of our report would be, and we assigned people to work on some of the areas, but it was really in a very skeletal form, and we wanted to really wait till we had heard more of a science before deciding on the structure of the body of the report. So I'm hoping that today we'll be able to hash through that in more detail, assign people to work on different parts of the report, and then go back to the committee as a whole with a real outline. So why don't we start on the letter. I've never written a letter with such a big group of people before.

DR. CHAPMAN: Can I say something? Part of what I heard in the discussion this morning was a lot of need for additional fact-finding about what actually is going on and where that fits in the context of what's going on and also what the most appropriate sort of advice or recommendations would be to give to the Secretary in terms of options. So I think it's a good idea to begin to draft something, but my thought would be that this will need to be something that will undergo rounds of review by the committee outside, that they should give us an initial draft mailing and thoughts about things to follow up on.

DR. MICHAELS: I maybe heard a little bit different. I thought that by the time we came out of the discussion, that we were going to draft something a little bit broader rather than just harping on Mexico, and the incident that we don't have all the details on was to at least bring to their awareness that this is an issue that's happening that we believe is happening in other countries, so we actually did want to get a letter out before we waited for the final report. But you're right. I think that it is going to have to go through the whole group, but I thought that we were supposed to -- I think we should try and draft something.

DR. CHAPMAN: What are you going to advise the Secretary to do in the letter? I think that was the part that seemed to need a little more looking into.

DR. SYKES: Maybe we can talk about that now before we write it. One thing that Dan brought up was trying to work through NAFTA. Louisa, you had made another suggestion to the Pan American Health Organization. The thing that occurred to me, the question of what do you do when they don't want to cooperate, was well, the one thing we can control is travel into the country, and if Cook Islands wants to do pig xeno transplants with no infectious disease monitoring, then we can refuse admission to the country from people from the Cook Islands.

DR. KASLOW: Excuse me, but I think we're talking about a couple of levels beyond where this committee is. Those are political decisions, economic decisions, that we're going to have very little direct influence on.

DR. CHAPMAN: Department of State decisions.

DR. KASLOW: Well, whatever. They're certainly not decisions for our committee. So it seems to me that what we ought to be doing is laying down some fairly concise principles of how we think we as an organization, as a committee, ought to be operating vis-à-vis other groups that have an interest in xenotransplantation outside of our country. So for example, one point might be that it would be useful for our committee to make appropriate contacts with other organizations to exchange information about what's going on, how they're developing their policies, all of the things that parallel organizations and

other places would be doing of the nature that we're doing here. That would seem to me to be an appropriate sort of overview of how we should approach xenotransplantation in xeno geographic areas, places outside of our country.

DR. SWINDLE: I would go a level higher than Pan Am. In fact, I would start off or say in there somewhere, follow the World Health Organization guidelines. To me that would be more comprehensive and not targeting a specific region or area.

DR. SYKES: I guess, Dick, maybe you should clarify for me because what you're describing is really suggestions for what we should do as a committee, but I think what Lily had asked us to do was make recommendations to the Secretary as to what can be done at his level at this point.

DR. KASLOW: Right. Well, there may be two parallel activities that would go on. One would be organization to organization. The other is government to government. I think that what we would be doing is taking more direct action to facilitate organization to organization interactions, and we would be making recommendations about what government to government actions might be taking.

DR. SYKES: That kind of assumes that there are organizations in every country, and I think the problem is there may not be.

DR. ALLAN: To me that is something we can get from -- if Harold, as he suggested, at the next meeting we discuss this in detail, I think those kinds of things are appropriate for that, like getting information on the Council of Europe, where they're at, where all these other international organizations are, where they're at, and that's good for the next session. But if we're going to write a letter, then I think we need to focus on what are the broader issues. In terms of making recommendations as to what to do about it, I think that's going to be the hardest part. I'm uncomfortable with that.

DR. CHAPMAN: I want to just say that what Richard was talking about are some things that this committee could do, but he's also talking about things that are directly relevant to the Secretary because the Secretary of Health and Human Services looks at the budgets of the different agencies, for example. In particular, this one is scrutinizing very carefully such things as why are tax dollars being spent on international travel. I think it is relevant to the Secretary to know whether this committee feels that it is money well spent or poorly spent to have staff at FDA or CDC participate in Council of Europe deliberations, European Union deliberations, WHO deliberations, because it's not a foregone conclusion that the Secretary's Office perceives us as valuable or not valuable. If this committee is saying those are very important aspects of the public health work, then that should be said to the Secretary.

DR. KASLOW: What I was suggesting is that the considerations that Tommy Thompson or anyone who makes a contact with the government of Mexico is going to go through is what kind of an organization does Mexico have that might be governing this activity, and have we had communications with that organization so that we understand what their policies are and how this activity that's going on and others that we may not know about might adhere or not adhere to their own policies? Those are the considerations that the Secretary is going to make before he, I would think, ever opens his mouth, let alone takes any direct action or suggests any to his superiors.

DR. SYKES: So would you then be asking in our letter to the Secretary for the go ahead to make those kinds of contacts so that we can pursue this?

DR. KASLOW: Yeah, that might be one option. Those are the kinds of things I think we should explore before we make a decision about how to write a letter.

DR. ALLAN: I think what you could do is we're not going to have that information to write a letter to Tommy Thompson. We're just not going to have any of that information. What we can do is at the end of the letter you can say, we're going to be meeting at the next advisory council meeting, and we're going to get this information, and that's something that we can do. But in the meantime we can still get the letter out and state that we're going to be looking into these issues in terms of what's going on.

DR. SYKES: But what I'm hearing is that we're no longer asking the Secretary to do anything. We're asking the Secretary for a mandate to explore this issue.

DR. SWINDLE: I think that's correct, and I think that's what we came to when we were sitting together as a group, is you're not recommending direct action on this protocol, using it as an example of what is actually -- we already heard about the Russian experiments where they did hundreds or thousands of people. So it's a global issue.

DR. SYKES: So we just want to bring this to his attention at this point and then take the responsibility back ourselves to explore it and advise him on this issue in the future.

DR. LUBINIECKI: There's another perhaps way to think about this, and maybe it would be useful to ask the Secretary if he in his official capacity would like to liaise with his counterparts and the government of Mexico and the Cook Islands and find the facts for the committee as opposed to saying the committee will find the facts and advise the Secretary because I mean this is, after all, a very wonderful group of folks, but it's only a committee, and our resources are kind of limited to the people in this room. I'm just not sure what we can meaningfully expect to accomplish on our own, and perhaps it's the Secretary's job to find out what the facts are and not ours.

DR. SALOMON: I'd like to add. I think there's an interesting line that we have to be careful not to cross, and I think that's what Tony is also getting at. One is advice, and one is strategy. We're an advisory committee and obviously not a strategic committee. I think it's okay to give advice. I think we ought not to be giving out a strategy. I think that's something I got from this morning's discussion and have taken to heart. The other question I had would be -- and I think this gets back to something Megan was suggesting, and I'm not certain of it. Is it within our purview to get maybe two or three of us and go down to Mexico City and visit and just get the information from the group down there? Would that be something that this committee would sponsor, a fact-finding mission if you will?

DR. MICHAELS: I think we'd have to ask Mary, and she's in the other room at the moment, but I think we should ask her. I think that's a good suggestion. One of the things that I'd like to see in the letter is just to -- I mean I think we're all saying it, but in terms of putting it actually into a letter is highlighting the fact that the infectious disease issues don't have boundaries, and if these are being done in other sites, that it is important for us to address.

DR. KASLOW: I think that's again another organizing principle of this. Why are we concerned about this? Obviously there are ethical issues, but there are ethical issues with clinical trials all over the world in all kinds of things. The issue that's unique to this is that it has a potential risk for people in this country as well as other countries and people who we are concerned about, so I think we need to focus on the things that make this unique.

DR. SYKES: I agree with you in this letter, but I think nevertheless as a committee, SACX should come up -- I mean if we're trying to come up with an informed consent document, I think we should be trying to come up with some ethical guidelines for what we consider acceptable. I don't think there's anything wrong with making a statement about that. I mean the IXA letter that went to the various journals, I finally did see a final form of that through my e-mail last night, and the upshot of all of it is a

recommendation that meetings do not accept abstracts unless there's some assurance that certain ethical guidelines have been followed, and likewise for journals. The IXA is coming out as a body and saying that. Likewise, I think SACX could come up with some guidelines.

DR. CHAPMAN: Can I point out what I think is a key difference though? The IXA is the International Xenotransplantation Association. It is an association of professionals from all over the world working in xenotransplantation, and they are making standards for their professional association around the world. This is a body of experts convened to advise the Secretary of Health and Human Services for the United States government on xenotransplantation policy issues for the Department of Health and Human Services for the United States government, so I think that may be an imperfect model for the mandate and the authority. In terms of the process I think the letter will not come from the ex-officio, so it's not my role to suggest to you what to say, but I think perhaps it would be helpful if I provide some information about process in terms of whether this committee could go into a fact-finding mission.

If the concern is a public health threat that may be posed to U.S. citizens by something that's going on in Mexico, what I can tell you about the usual process of the way that would be dealt with through public health agencies is CDC, for example, is our federal public health agency, but all of the regulatory authority within the U.S. in our area belongs with the state health departments. So if I was called at my desk about this going on in the state of Alabama and the concern that we need to do a field investigation to look into it, or in the state of Georgia, in Macon, Georgia, we would call the state health department, make them aware -- this is within the U.S. --make them aware that it's come to our attention that there may be this problem that bears looking into. They would look into it. They would decide whether they could manage it on their own. They would decide whether they would want our help with it. If we really thought it was important for us to be involved in the investigation, we often in fact sort of solicit those invitations, but even within the U.S., we operate within a state, even within the state of Georgia where we're located, at the invitation of and as deputies of the state health department. The usual way we would work with something in another country as public health authorities -- and this committee is not exactly a public health agency, but just the way we would do it would be by communication with our counterpart health authority within that nation. And even within states within the U.S. we operate within the state in field investigations, which is sort of what you're talking about. At the invitation as deputies of the state health department you can imagine that that's even more so at the international level.

Now, I don't know how good a model that is for a committee such as this because you're not government employees except operating on this committee you're special government employees, but that would be the usual process to go through, sort of like what Dr. Kaslow was suggesting, through contact with the organizations or groups or individuals who have authority for that area in that territory.

DR. SYKES: Well, as you point out, we are not a public health organization. We're not full-time government employees. Is there an agency at the national level that you would suggest to the Secretary be the one to make this contact?

DR. CHAPMAN: Any public health agency in the U.S. is under the Department of Health and Human Services, so you could simply suggest to the Secretary if you thought he needed to investigate or look into things, he would have at his disposal the option to draw from any of the federal employees regardless of agencies that are under his department.

DR. SALOMON: So Louisa, just in terms of strategy, certainly the last thing in the world I was suggesting is that we go down there as public health officials and investigate. If I used the word investigate, I didn't think I did, but if I did, I apologize and retract it. What I mean only is as part of the job of doing our job of advising the Secretary, we heard from several people that they thought we needed more facts. My view is that if you approach the Secretary saying, we know this is going on, I've spoken

to Sir Roy Kahn who came and presented this data at Scripps about three days after -- he came from Mexico City to San Diego. I mean I know what's going on in broad strokes. He presented it in a constructive way. We know this is going on. We want to reach out and help. We want to just liaison, create harmony, et cetera, not investigate, stop, any of these dramatics. Alternatively, if we really say, we really want to know all the facts and make an informed decision, I don't have a problem with that either, but within that process we're going to need to either bring them here or a couple of us go down there and just talk to him. I mean like I said, it can be rather informal.

DR. ALLAN: I want to lay this out, and I want to separate everything. There's three different areas here. The first is a letter. The second is maybe going to talk to Tommy Thompson. The third is what we're going to do at the next session. What I'd like to do is sort of try and split those apart. What you're talking about is what we need to talk about in the next advisory committee. Then what you're talking about, which is to make recommendations or something, really is part of what Harold would do to go talk to Tommy Thompson. That's not immediate either. So if we just come back to the letter, I think what Lily was talking about was look at it in a broad sense, give him the information about that this is going on, and my opinion is we don't have to make recommendations as to what he should do or anything at this point. We just want to give him our strong sense of what's going on and that this is a real danger and that our committee is looking at this.

DR. SCHECKLER: Can I suggest some language for a letter?

DR. SYKES: Yes. By the way, I have no intention of taking upon myself to draft this letter. I was hoping that we would do it as a group right now.

DR. SCHECKLER: I'm sitting here trying to draft some language for my friend Tommy. Here is at least a start because I can't deal in theoretical. I need a draft. As the science of xenotransplantation develops, it is important that the international community involved in developing these procedures implement -- I'll give it to you. Let me read it and see if it's off the wall or something you want to develop. And they're better at transcribing this than either one of us. As the science of xenotransplantation develops, it is important that the international community involved in developing these procedures implement processes that assure the safety of them as well as their possible benefit. There's too many redundancies there. For the public health, the potential risk of transmission of infection is an important risk SACX has been addressing in its meetings.

It would be useful for members of our group and the relevant federal agencies, such as the CDC and the FDA, to be sure to have access to information about xeno trials such as those being done outside our borders. Actually of xeno trials being done outside of our borders. For example, in Mexico, Cook Islands, China, whatever other specific examples would be relevant. To assure that U.S.A. citizens are safe from infectious disease risks. We recommend that your office facilitate data gathering under the auspices of the appropriate public health and regulatory agencies in those countries where our citizens may be obtaining xeno transplants.

So the concept here is to make sure that we're connecting the dots, that we're connecting our agencies with the appropriate agencies in those other countries, whatever they are, public health or regulatory, if they exist, which is sort of a heads up if their aren't any, that's a problem. That's done at an international level through pot hole or through some of the other world health organizations or whoever. The tie back is that our citizens are getting transplants in those countries -- we already heard about that -- or potentially have transplants. And we spent a lot of time anguishing over one of the reasons this committee exists is because of the theoretical risk of infection and transmission, and that's the tie back.

This is a fairly benign approach, but I don't think that we have -- I mean that's the recommendation to the

Secretary. We need your good offices to make sure that we're connecting with folks in Mexico and China and what have you. That's kind of what I heard from Lily. The issue of the face time with Harold and/or other members of the committee and the Secretary, that's the way Tommy operates. He has short meetings with people. He wants brief briefings. He doesn't meet with whole committees. He meets with sort of individual people and to sort of know where we are. And I agree that that's a bit down the line, not for this issue. But this is kind of a heads up, and I'm assuming, frankly, that Lily does this already, but I think it's useful for us to get something formal in writing. That's where I am. So here, pass this down to Megan.

DR. CHAPMAN: This letter might be a place where the committee might want to include any thoughts it has about how it would encourage the Secretary to use the resources of the department that are at its disposal, and that would include the budgets for the various agencies, the salaries of the employees, travel costs to participate and things like the Council of Europe or the European Union deliberations, the WHO deliberations. Organizations like WHO and I assume PAHO also generally operate with minimal budget, and special initiatives have to have funding committed by member nations, so one other root I'll just lay out to the committee is if you think there are initiatives that should be pushed through WHO or OECD or PAHO or some other international organization, you might think about whether you want to advise the Secretary on whether this committee would consider it an appropriate or inappropriate use of U.S. tax dollars to support those kinds of initiatives.

DR. ALLAN: I'm not so sure we want to be that specific. I mean you're talking about dollars and cents, and to me I think we just want to be more broad, and that can come up at a later time in terms of how you're actually going to institute it on a real specific level. I mean I agree with you, but I don't know that in this letter we want to be getting into the details.

DR. WILSON: I wanted to just make a few comments, since Eda's in the other room, in terms of how the FDA may be involved in some of these types of issues. Unlike the system that Louisa described with the CDC and having to defer to the states, the food and drug law in contrast gives us national authority as long as the manufacturer of a product enters into interstate commerce. And so in contrast to what Louisa described for CDC, FDA can do local investigations without having necessarily to go through state channels. Not that they wouldn't necessarily notify state authorities and work with them, but that we do have national -- that their laws are different in that regard. And secondly, if a procedure that's being performed in a different country is being advertised, for example, on a website and therefore could potentially be recruiting U.S. citizens, there is a precedent for FDA also getting involved. And the third point I wanted to make is that I know that we have in our center an international liaison who -- there are certain countries that we have already agreements in place for liaising with their regulatory authorities so that we can exchange confidential information because the FDA is again required by law to maintain trade secrets in confidentiality. I just wanted to provide those additional points for clarification of how our agency operates.

DR. SALOMON: Before you step down, can you add one more thing? Can you teach me what is the line between the Secretary and the FDA? Is there some sort of a legal issue that they can't tell the FDA to do anything or can the Secretary suggest to the FDA to do this? How does that work?

DR. WILSON: I know that we are, quote, an independent agency, but Eda or maybe Louisa knows better than I do exactly where that line is.

DR. CHAPMAN: The commissioner of FDA, the director of CDC, the director of NIH, the director of all these agencies, all report directly to the Secretary of Health and Human Services, so he's the next person up their chain of command. Further, they're all presidential appointees, but I presume they are appointed with the advice of the Office of the Secretary or certainly with the agreement with the Office of

the Secretary. Now, in terms of what authority he has to demand that agencies do various things with FDA, I presume largely for FDA as a regulatory authority, that's determined by the written laws. If the legal authority is there --

DR. KASLOW: Way back in my bureaucratic days I remember that there might have been, whether it still exists now, a distinction between the food and drug commission, because he is the commissioner, as opposed to the other public health service agencies, but that distinction has long since escaped me in terms of the current day-to-day practices, so I have a feeling it operates like any other agency as a part of the Department of Health and Human Services.

DR. CHAPMAN: But again I think the committee needs to think about what directions they are advising the Secretary to move in, and then the Secretary has at his option disposal, if he chooses to take the advice, to operate through any of the resources under him, which includes agencies, personnel, whatever, whichever is more appropriate for the action.

DR. KASLOW: I would suggest that Bill's offerings in draft language is a real good start. It might be worth our thinking about another element, and I don't know where it would fit, and that is that it isn't just our citizens who are directly involved as potential consumers, but the broader issue of whether the actions taken, for example, in the Cook Islands where it's unlikely that any of our citizens are being affected, still has the indirect impact of potentially creating infectious risk to which citizens of this country and other countries are all risk. So our country as an entity has an interest in what goes on there in the same way we have an interest in the Quito Accords and what happens to our environment when another country pollutes their local air space or water or whatever.

DR. MENDEZ: I think there's also another aspect of it that we should at least make the Secretary aware of, and that is not just that our consumers may be going to foreign countries to obtain allografts or xenografts, but that there are collaborative efforts underway or relationships that may be developed between our xenograft-producing companies and organizations with foreign countries. I know of a couple of instances in which contracts were issued in which the work is actually done in the United States. The isolation purification, the type of things that they cannot perform in the foreign third world countries, and then the product is shipped across to other countries so that there is a relationship in which we may want to make the Secretary aware that we participate, and maybe at arm's length, but we have a collaborative effort. So it's both sides of the coin. It's both the recipient and the donor.

DR. MICHAELS: But we're not saying that international collaborations could not occur as long as they're occurring within the purview of having recommendations and guidelines.

DR. MENDEZ: Right.

DR. SYKES: How does that work now? I mean right now if one wants to do a trial abroad from an academic institution, it has to go through the institution's IRB. But for a company does the FDA provide that kind of oversight for an overseas trial?

DR. WILSON: The food and drug law actually does have a provision in there for if you're exporting a drug for human clinical use, that there would be some oversight of that.

DR. SALOMON: So Carolyn, here's the possibility. I start a company, the Dan Salomon Company, and I've got a technology. I make a deal in Tijuana. I set up a little room down in Tijuana. I do the whole thing down in Tijuana. Do you have anything to say?

DR. WILSON: The FDA is supposed to review the export license.

DR. SALOMON: I don't export anything except the technology.

DR. WILSON: Oh, I see your point.

DR. LUBINIECKI: One of the times when the FDA would also get involved though is if you wanted to bring the data back to the states to use it in support of a market application or an IND. Then the FDA would be involved in looking at that data.

DR. SALOMON: But you've got to admit it be very interesting. Right? I go down to Mexico, treat 20 children, cure 18 of the 20, come back to the United States and say, now stop me. I mean there would be such an outcry, everyone would be screaming, you've got to let the guy go. Right? I think the principle here and what I was getting ready to say, and Bob started it perfectly, and that is one of the other principles here, to add to what Richard articulated, is how do we want to be involved in the responsible advancement of testing of new technologies? There's the lentiviral vectors, the HIV vectors that we're dealing with in the BRMAC committee. Take it down to Mexico and do the study. We really have to grapple with this. I'm not saying that I've got an answer for you. It's just that I think we ought to defend that principle as well.

DR. ALLAN: I think in the letter what we really want to make clear is that this is just not another medical technology that's being done outside our borders without no regulation. We want to be very specific of the serious nature of the infectious disease risk of xenotransplantation technologies, and we want to be absolutely clear about that. So I would use terms like we want to alert you to these types of situations. I think we'd want to use a strong enough language that it's very clear when he's just flipping through this page that it's like oh, this is different. This is something that I really want to pay attention to.

DR. LUBINIECKI: I think we should also add that it's not just our feeling, but it's also the feeling of the International Transplantation Society and include a copy of their letter to the New Zealand health authorities.

DR. PRASAD: To make this a little more concrete perhaps, if we're talking about U.S. citizens or residents getting transplants in foreign countries, later today Dr. Dayton is going to talk about the guidance for deferral of blood product donations from the xeno transplant recipients, and this is perhaps something that we could link into the comments in this letter.

DR. MICHAELS: I think that's great. So to put it in very concretely, the infectious disease risks are serious enough that any individuals that receive these transplants will be deferred from giving blood products, so that could be in there as an example of how important we take it. Or no?

DR. SYKES: I think the letter is getting long and diffuse once we get into that because we can't say will be. That's a recommendation that's coming out. So it gets into a lot more words I think.

DR. MICHAELS: Then where are we with the letter?

DR. SYKES: Well, I'm going to let you guys draft it. I'd like to go from start to finish. Since nobody was talking about the first part of the letter, I was kind of working on that while we were talking. It's rough. I haven't even read it.

Dear Secretary Thompson, as your advisory committee on xenotransplantation, we are writing to advise you of a concern that we believe deserves immediate attention. Since we have not yet had the opportunity to advise you of the activities of SACX, we would like to begin by informing you that we have working

over the past year toward the development of a report to you. Toward the development of this report, we have gathered information on the potential public health impact of xenotransplantation, the available alternatives, the risks in the state of the science of xenotransplantation. The anticipated report will also contain recommended consent form language for xeno transplants. Our deliberations thus far have led us to the view that xenotransplantation has tremendous potential to have a major beneficial effect on public health. The science of xenotransplantation has made enormous progress in recent years, but there are many areas of additional research needed before it can realize its full clinical potential. Recent advances in genetic engineering technologies have greatly increased the promise of this technology or this approach. That's as far as I've gotten. The next part was going to be a paragraph about the risks associated with it.

DR. ALLAN: The thing that I worry about, and someone told me this just recently, because I don't get it very easily, but I wrote a letter to my president of the foundation about some issues that I had, and I had a whole bunch of them, and I wrote like a three-page letter. And then I told this other person, this wise Bulgarian woman, who's a pathologist, and she's retired, and I told her about it, and she goes, huh-uh. She said, you know, one issue. Stick to one issue. Stick to one issue. Because if you bring in more than one thing, then it gets lost in the message. So what I would suggest is I understand what you're saying about putting all of this other stuff in there, but I think we want to alert the Secretary that this is -- I mean why are we writing this letter in the first place?

DR. SYKES: We've started the letter with a sentence saying we're writing about a concern that we believe deserves immediate attention. Then there's a short paragraph saying what our activities have been simply because we've had no contact with them before, and we don't want to just come up with this negativity about xenotransplantation as the only thing we say to him in our first contact.

DR. ALLAN: I agree. But the thing is you've got the first sentence that says, we have this concern, and then you've got to read all the way down before you find out what this concern is.

DR. SYKES: This paragraph's short. That's it. It's done.

DR. MENDEZ: I think it's just excellent.

DR. MICHAELS: I have to agree with Megan.

DR. MENDEZ: We haven't had any contact with him yet. We have to tell him a little bit about we have some validity of having some concern.

DR. SYKES: So now the next paragraph should begin with however. That will get his attention. Okay? So does someone want to dictate the beginning of the risk paragraph?

DR. SALOMON: However, it's come to our attention through firsthand --

DR. SYKES: I'm sorry. Before we get to the international issue, that's the third paragraph. The second paragraph should be the general risk. So however, the enormous potential of xenotransplantation does not come without significant risk to society. How's that?

DR. MICHAELS: That's a great word.

DR. SALOMON: I think I used the word shadow, the shadow of the tremendous benefit. It's shadowed by this risk of potential public health risk.

DR. MENDEZ: I'd use the word potential risk.

DR. MICHAELS: We'll be able to edit it. Infectious agents within the donor cells, organs or tissues. I'm sorry, xenogeneic. Keep it simple. Or you could say, animal donor organs, tissues or cells.

DR. SALOMON: Yeah, just animal organs.

DR. MICHAELS: Okay. May be transmitted. We'll have to edit it because I think we're going to have potentially like five times in one sentence or two sentences. To the recipient. To the human recipients.

DR. ALLAN: And to the public.

DR. MICHAELS: I would think that's another sentence. If this occurs, the infections may be able to replicate in the recipient and be transmitted to contacts.

DR. ALLAN: I would cut out replicate. I would just say, transmission to contacts with the risk being to public health.

DR. SALOMON: A phrase like an unknown public health risk. That doesn't commit us to anything, and it's scientifically proper.

DR. MICHAELS: The Public Health Service of the United States. As you know, the Public Health Service of the United States government has been extremely active. Okay. Not extremely?

DR. SALOMON: I have a new filter on my word processor at home for all grants. It goes through all my grants and removes extremely, very, novel, interesting.

DR. MICHAELS: Of screening tools of safe policies and practices to ensure the safety of the recipients and the public at large.

DR. ALLAN: Do you want to be specific and say FDA regulations on xenotransplantation and PHS guidelines on xenotransplantation?

DR. CHAPMAN: You could do that, or you could sort of speak more broadly and refer to that and just say, the public health service has been involved both in developing domestic guidelines and guidances which would incorporate the PHS guideline and the various guidances of the FDA, and you could also refer that PHS has also been actively involved in working with international organizations with WHO, OACD, the Council of Europe, the European Union.

DR. KASLOW: Megan, I wonder if it might not be a little more efficient for us to try to get the major phrases down. We're not going to be sending this letter out this afternoon. Couldn't we get the major ideas and concepts down and maybe have two or three at most people on the committee draft a letter and circulate it to all of us to review and edit? Then we can move on to some other stuff that I think we're going to want to try to get done today.

DR. MICHAELS: I don't think it should just be the PHS. I think it should also be that federal agencies, but also I think that he should know that researchers in the field of our country have been very active in all of these groups as well, the professional societies, and in the international societies, and then some of the names of the international groups. All right. Forget the societies then.

DR. SYKES: So the public health services as well as individual biotechnology companies and academic

scientists or something like that?

DR. ALLAN: Could you begin the sentence with like due to this perceived infectious disease risk and then go into the public health agencies and just introduce it?

DR. CHAPMAN: I think you do want to mention the professional societies, Megan, because they have actually, at least in terms of interactions with the government at every significant stage, there's been major thoughtful comment from the transplantation --

DR. SYKES: I'm on the council of both the transplantation society and the IXA, and we're working towards an ethics statement to the IXA, and the transplantation society I don't think has made much --

DR. CHAPMAN: Well, both the American Society of Transplant Surgeons and the American Society of Transplant Physicians prepared very long and thoughtful responses and public comments in response to the publication of the draft of PHS guideline in 1996.

DR. SYKES: That's the American. I'm talking about the International.

DR. CHAPMAN: But you're discussing a letter that the International Xenotransplantation Organization has sent out in response to that. So I think you do want to mention that the organizations have been involved. I would also say that the individual researchers who have been involved are generally in the leadership of these organizations.

DR. MICHAELS: Maybe we don't have to mention all of the organizations because it will get too long, but right, I think that Louisa's point is well taken to just mention them.

DR. SCHECKLER: As you are trying diligently to make it just right and get everything in there that everybody wants, like the wonderful promises of xeno and so forth and so on, I think we're kind of losing sight of what it is that I understand the problem to be.

DR. SYKES: This is going to be the final.

DR. SCHECKLER: I understand the problem to be that there are folks around the world that we don't think are paying attention to the source animals, the source tissues, in terms of the infection risk, that there is at least a real possibility may be spread to the recipients of those that we have in this country and the scientists, and many of them internationally been screening all of these tissues carefully and looking for these risks and putting in place guidelines to deal with these risks, and the heads up, Tommy, is that this stuff is going on around the world, and it would be nice to get more information about those risks and the tissue sources and what these other folks are doing through the agencies in those countries. That's the heads up. This is putting our folks at risk, and it's putting others at risk, there's a potential international risk, and that's the heads up. And get rid of all of the other obsessing about the language and getting it just right. Tommy will want to know what's the heads up here, and what should I do? And don't give me all of this advertising for xeno.

DR. MICHAELS: I think that we can shorten the paragraph, but I think something has to be in there just to let him know and then have the next paragraph start, these intense national and international efforts can be undermined by the fact that, and then go into your paragraph. Is that okay?

DR. SCHECKLER: Brevity is the soul of wit.

DR. MICHAELS: Then we'll send it around and shorten it.

DR. SALOMON: I'd like to go on record as saying the less fluff, the better. I mean it's already now four paragraphs till you get to the point. I think it should be one page.

DR. SYKES: No. It's two before.

DR. SALOMON: Still I don't think there's tremendous promise in xenotransplantation right now. I think that's getting back to the cheerleading function of the committee. You're personally welcome to have that position, and that's good, and you can defend it. I don't know that that's what the whole committee wants to communicate to Tommy Thompson. It certainly wouldn't be the way that I'd put it. I think that the main issue here is that there is a way to do this, that there has been an agreement in every developed country on both sides of the Atlantic that this is something that can't be taken lightly and deserves an overarching regulatory environment for a well-designed trial that involves issues on the animal side and on the ethics and on the monitoring of the patients, and that we have concerns that that kind of a regulatory framework doesn't exist in Mexico and in many other countries where these trials should go, and that we need more information. That's what we are worried about, period.

DR. KASLOW: Absence of those conditions in those places potentially poses a direct risk to our citizens and an indirect risk to our country at large.

DR. SYKES: Do you guys want to just sit down and write it out? Why don't you take Bill's language, take your language, and incorporate it together into a paragraph.

DR. ALLAN: The other thing I think should be in there is there's been over eight years of discussions and meetings and refinement of these guidelines and regulations that have gone on in this country and other developing countries, and the major concern we have is that this isn't happening in these other countries. So I would make sure he understands that this isn't something we just came up with. This is like eight years of discussions, and these people just ain't doing it. And the other thing is the immediate thing too, which the fact is that these things are ongoing, these are ongoing trials in Mexico and other places.

DR. MICHAELS: Are you able to give us a copy of like the statements that Dan just made and Dick and Jonathan so we have it typed up? Is it possible for us to get it? Will it be in the minutes so that we could just highlight that paragraph, somebody could take it and work it into a letter? Because it's not fair for Megan.

DR. GROESCH: It will be in the transcript, but it will be at least a week before it's available.

DR. CHAPMAN: Well, this letter won't go out in a week. You need a draft for various people to revise and edit.

DR. SYKES: I have to reiterate that I feel very strongly that the first paragraph should be an introductory paragraph like the one that I read to you, that does state some of the potential of xenotransplantation. I think that if we come out with a letter that does nothing but say, there's this terrible risk, as our first introduction to the Secretary, it would be a big mistake.

DR. KASLOW: Megan, it goes without saying though we wouldn't be here if we didn't think there was a potential benefit for it, and I think we can in one or two sentences state that. I'm not worried that this is going to be too long because we've added a positive comment about it at the beginning. I don't think you need to worry about that. We're all in favor of that.

DR. MENDEZ: I agree with that. I think it should be a positive statement at the beginning and then our concern. Frankly, I wonder if he's going to read this letter and say, this is an international issue. What sort of clout do I have or what can I do about this? He can weigh his moral support perhaps and talk with his colleagues in other countries. Bill would probably know better how he would address that. He might look at it and say, well, this is out of my jurisdiction, or will he take a look at it and say, well, there is something perhaps I can do about it, or is this how we couch it in the letter?

DR. SCHECKLER: I think you're obsessing over the letter too much in exactly how it's worded, and I think Lily should be helpful here in terms of getting the message to him. I think the action issue is what Tommy would be interested in. What should I do? And if we need to have our folks in the FDA, the CDC and from this committee make sure that they have all of the information from these other countries, they're a regulatory and public health agency. This is a heads up. This is an important issue He has liaison staff with PAHO and with other organizations that can do that. Sometimes they're even through the CDC or through existing federal agencies. So he'll ask his staff, all right, how do we get this information to these people?

DR. SYKES: Bill, if I give you back what you've written, would you be willing to take that and complete that final paragraph?

DR. SCHECKLER: I mean I already gave it my shot. I'd like somebody else to sort of look at it. I don't think it should be longer than a page. It should have some bullet points on it. That's the other thing I've learned with Tommy and many politicians. They don't like dense paragraphs. They like bullet points.

DR. KASLOW: Bill, you're the guy. You just wrote it for us, so just put it down on paper.

DR. SCHECKLER: I did. It's there.

DR. CHAPMAN: I'll remind you of Lily's comment earlier where she encouraged you, for exactly the reason that you raised, if you're going to send this letter to the Secretary as his advisory committee, that you take the time to clarify in your own minds what you are advising him to do in response to this situation. It may not be on the detailed level, but in broad strokes. He does actually have staff. Regularly his minions at the FDA meet with and work with the Council of Europe on their developments, and that's been going on for many years. His staff from FDA and CDC have been actively involved in the WHO guideline development that started back in '97 from at least those two agencies and perhaps NIH with the OACD work that went on. So that's one reason I was suggesting that it might help the committee in developing their letter to get the intent, the effect that you want, to take some time to do some more homework on these sorts of things. But again you can do that in broad terms. I mean I'm not sure what this committee wants the Secretary to do once he knows about this, but if you want to encourage him to use the resources at his disposal to work with international organizations or Pan American organizations that harmonize regulatory authority or control, then perhaps you should state that. If you want him to use the resources at his disposal to work with other organizations or review the funding through NIH which funds trials I understand both nationally and internationally, you should state that. If you want him to liaison with his colleague at the department of state, if you're trying to develop this into a state department issue, then you should state that. I think what Lily was trying to suggest is that if you want to have an impact with your letter, you need to think through, at least in broad terms, of what you would advise the Secretary, what direction you'd advise him to move in in response to the information you're sending him.

DR. ALLAN: Do we even know what we want him to do? Bill was talking about asking him for information. I'm not sure how that would look in terms of what we're actually asking him for. I mean more information, is that what we want?

DR. SWINDLE: I think you can put it another way, to support harmonization of these various international agencies. For instance, I have no idea what kind of clout the WHO has. I mean they're just guidelines, but they aren't going to send police in and force them, right? All these nations are members of WHO, right? So it seems like if you asked him to support harmonization of the existing international guidelines, you're not asking him to write something new.

DR. ALLAN: What does harmonization look like?

DR. SWINDLE: My family life at home.

DR. CHAPMAN: Carolyn, I know the FDA has had over many years a big effort at getting international harmonization. Are you in a position to speak to that?

DR. WILSON: There is something called the International Conference on Harmonization that involves the U.S., Japan and the European Union. It's been primarily directed at sort of the biotechnology recombinant DNA drive products. They're just starting to discuss extending it to include things like products that involve gene transfer and potentially cellular products, but xenotransplantation is probably still several years off before that would be coming under this umbrella of ICH. What the ICH does is basically it comes up with a common framework of what information the governments in each of these countries would require somebody to supply in request for a marketing application so that companies don't have to come up with broadly divergent sets of information for different countries when they want to market. So it's also a little bit further down the road. It wouldn't apply to a phase 1 clinical trial in other words.

DR. SYKES: How many countries are in that, and does it include Mexico?

DR. WILSON: No, not to my understanding. My understanding is it's U.S., Japan and the European countries.

DR. LUBINIECKI: Although Canada has agreed to abide by the things that are agreed to. One thing I think that we could possibly ask the Secretary, in addition to liaising with Mexico, China, Cook Islands, whoever, is to not only get the information, but also bring it back to the next meeting of this committee so that we're aware of it and therefore can provide him the best advice possible.

DR. ALLAN: Dan, do you have any suggestions?

DR. SALOMON: I'm writing.

DR. SYKES: Sounds like we've exhausted that topic. It really would be good if we could come up with what we want to ask the Secretary to do before we wrap it up. I mean I think that's really key to this letter.

DR. MICHAELS: We recommend the Secretary of Health and Human Services to encourage investigators to work within guidelines of -- I don't know what the correct word is here, if someone could fill in the blank -- of countries that have reviewed guidelines and discourage rogue -- but rogue isn't the right word either. I'm trying to put a positive spin. To encourage countries to work within guidelines that have been set forward by international committees, by national and international committees, and discourage individuals working without guidelines.

DR. CHAPMAN: So are you suggesting, Marian, in terms of what's at his disposal to deal with, that he review the policy and procedures of DHHS funding for research to ensure that appropriate safeguards are

in place, that investigators who receive that money comply with? Are you suggesting that he consider whether it is important to move the efforts for harmonization of regulation to extend into developing nations, in particular, Pan American, or to initiate efforts of Pan American harmonization of these sorts of regulations?

DR. MENDEZ: You might want to use this vehicle as an encouragement to fund or to look into more vigorous funding of the possibility of zoonosis or various infectious problems with xeno transplant, to speed up the process of looking at this potential risk.

DR. SYKES: I think we're losing sight of what we started out wanting to write to him about, which is the concern that xenotransplantation is going on in other countries, and we have no way of knowing how that's being monitored, and we're concerned.

DR. KASLOW: I think what we can do is to encourage the Secretary to convey our concerns, and the way he would do that would be to operate through the executive branch of our government in a government to government interaction, and they're cabinet level decisions, and the way we would use to communicate that to the president of Mexico might well be different from the way we would communicate it to somebody in the Cook Islands for example. So all we can do is advise the Secretary to consider ways of communicating our concern about the risk to not just our public, but everybody's public.

DR. ALLEN: Those could be the bullets that Bill was talking about, possible avenues, and then boom, boom, boom. That's what we're going to have to try and get more firm on is what they are.

DR. MICHAELS: From the NIH side, I mean right now the NIH would not fund a protocol that did not have the appropriate institutional review board, right?

DR. PRASAD: Right.

DR. MICHAELS: If there were any American citizens that had NIH -- investigators that had NIH funding that were participating in these programs that were not under an institutional review board, it seems that they would lose their NIH funding or only if it was directly related to that NIH funding.

DR. PRASAD: Right. In cases where it was an NIH funded investigator doing these trials, NIH would have oversight and would require that the funded institution's IRB grant approval, but we're talking about a situation that is not occurring with NIH funding, and what authority the NIH or any U.S. government agency has over these trials, we probably don't have any authority other than in terms of advice. But the issue as I see it here and as Dr. Kaslow mentioned is protection of the U.S. population from potential risks of these xeno transplants, and I think that since the letter is being framed in the context of those risks, perhaps the advice should be framed also in that context to what can be done to protect the U.S. population from these risks, and it may not require that you have specific items because then we can spend the rest of the week discussing what those are, but perhaps some general statements on that.

DR. SYKES: I think what Richard suggested is just the right level of generality because we don't presume to know what avenues could be pursued at the government to government level. I mean that really is for the Secretary with his participation in the government to figure out. I think that would be a very good bullet point. Is there anything else that we want to ask him to do that we agree upon? I know we've had a lot of suggestions. I don't know if we've all agreed on any others. Have we all agreed on this?

DR. CHAPMAN: Maybe you can use your larger report coming out for the issues that you feel need more thought. I mean you can refer in the letter that we encourage you, and we're working on a larger

report where we may have more specific suggestions.

DR. SYKES: So right now the one suggestion and then tell him there's more to come with the report.

DR. MENDEZ: I would really agree with that because this is our first contact with him, and we want to be not completely negative about things, but a little upbeat because this initial contact may in some respect create his opinion about our organization, our committee, and the views that we're going to give to him later on. That's why I like Megan's first paragraph. I do think it's important to be positive in your initial contact with anybody and then your concern about it.

DR. KASLOW: One very concrete action that could be taken or considered, and I'm not suggesting it should, but just as an example of how a recommendation might be phrased is that subjects, patients who are receiving a xeno transplant, an organ in Mexico who are United States citizens, or for that matter Mexican citizens, who are entering this country after receiving those organs, if they'd been following the guidelines of '96 and following, would be subject to monitoring according to the guidelines that we've created for clinical trials and so on. So the question is should our government, whether the public health service through quarantine officers or the immigration service, be taking any steps to identify those people who we are suggesting might pose a risk? Those are the kinds of concrete issues that the risk we're talking about translates into. So the question would be is there any advice we would want to give about any of the subjects of the transplantation procedures that are going on right now?

DR. ALLAN: I think that would come up in the next meeting if we're going to address these issues.

DR. KASLOW: I'm just giving an example of how we would think about it.

DR. ALLAN: But in terms of this particular letter, I'm still stuck.

DR. MICHAELS: Did you get his suggestion? What were you specifically asking?

DR. LUBINIECKI: In addition to asking him to confer with these other governments, that we also ask him to find out what level of monitoring, what level of oversight is occurring and to report back to the committee.

DR. MICHAELS: What about any information that he does learn, that he report back as opposed to asking him to. I don't know.

DR. SYKES: I think that what you're saying really ties in with what somebody else said earlier, which was to ask him to use the resources of the public health service to gather more information on this and have them report to us.

DR. SALOMON: I wrote something more. I'll send it to you by e-mail, Megan. The last part I said is, we suggest two actions at this time, first, that appropriate intergovernmental contact be made at the highest level in Mexico, New Zealand, the Cook Islands and China, to determine the kinds of regulatory frameworks and plans that are in place for these experiments, second, that we determine how we can be positive and constructive in providing expertise and support to ensure that these trials of a new technology are done safely and well.

DR. MENDEZ: That's very good and very positive. I like Richard's comment though on perhaps it's too much to put in that first letter about monitoring individuals coming back to the United States.

DR. SYKES: So everybody's happy that we've covered the main things that we want?

DR. MENDEZ: This is a picky thing, but instead of using the word report back to us, could we use the word inform us?

DR. SYKES: Yes. Okay. So on to the next area, which is the report. Just looking briefly at the notes that I took last time, we had divided the report into three sections, at least our part of the report. The first was the potential public health impact of xenotransplantation. I believe Bob and Bill had agreed to take responsibility for that part. The second part was the science, and that was the part that we had the least developed because we really hadn't heard everything that we heard yesterday. And then the third was the infectious disease risks, and I think we decided that Jon, Marian, Tony and Dan would work on that part. At this point I think we're still a little unclear as to what sort of report we'll be writing, i.e., what size, how much detail will be in it. Does anybody have a better sense than I do of what it would be? I think that for the Secretary's consumption we probably want something relatively short and concise. Whether that should be a accompanied by a longer document that would then be published, perhaps we could prepare a summary from a larger document for the Secretary or whoever else would want to read a shorter version and then have a longer document for publication after it had been approved by the Secretary. Do people have feelings about what they would like?

DR. ALLAN: One of the things that I think about is that there's a whole boat load of documents out there already that talk about infectious disease risks and talk about some of these other issues, and we don't want to just make another one of them. So the question is how would our documents or our reports be different in terms of being able to inform him of what it is that he needs to know, and what is it about our committee that is unique that can give him that kind of information that he's not going to get through these other reports that are already out there? That's really to me going to be a difficult process.

DR. SWINDLE: My feeling on this would be that you're either confirming the accuracy of the existing guidelines, that these are good guidelines that should be followed, or we're recommending that they go back and take a look at this issue within their guidelines. In other words, in the context of what he said is eight years worth of committees and organizations meeting, kind of analyze what's out there and say, this one doesn't go far enough or this one goes too far. Something along that lines would be my idea of a report. And then when you're looking at the international arena like we're starting to look at with this letter, there no one has addressed these particular public health issues, and there we might start making the specific recommendations, immigration questions, things like that, within the document. That's how I would view it.

DR. SYKES: You're really describing the infectious disease part of it, that that should be an analysis of existing documents and a real critical analysis.

DR. SWINDLE: Yeah. And where do we need to go from here given that we know that this is going on in countries that may or may not be following any guidelines?

DR. PRASAD: In terms of the overall report content and construction, I think the one place that this would differ from a lot of the other things that the Secretary has is that it would be focused on xenotransplantation. At the NIH we've put out or contributed to a number of reports on transplantation as a whole, and I can certainly provide samples of those to the committee. One of the crucial points in terms of construction, as you were talking about a short or long version, it's very important to have a one to two-page executive summary at the beginning that bullets the highlights of the rest of the document because chances are the Secretary isn't going to read the entire thing. It would be someone on the staff.

DR. SYKES: Should we try to generate an outline at this point? We've got about 40 minutes or so left. Should we just try to work through an actual outline? Bob and Bill are conferring over there. We're

going to run through an outline. Would you like to start?

DR. MENDEZ: I think we're waiting to see what the body of the report would be so that we could construct the introduction to state the things that we would be describing in the report and our thoughts about the report. Otherwise, we would be developing the outline of the report.

DR. SYKES: Actually I think what we discussed that would go into your section, I mean that would not be just an introduction to the report as a whole, would be a description of the organ shortage, some real information on that, so the need issue and the potential public health impact of xenotransplantation, and then the alternatives as well in that same section.

DR. SCHECKLER: Right. I had understood, and this is my total note from November 30th of the to do list, that Harold had already some sort of an introductory draft or language that he thought might be a useful starting point for us, which I never got and didn't try to get. Neither Bob nor I did anything to be honest because we're sort of waiting for somebody else to do something. And other things got in the way.

DR. MENDEZ: I have a five-day vacation coming on.

DR. SCHECKLER: Megan, your understanding was what I sort of remember, looking at this note now, that it was an introduction. What I didn't have a good sense of and what I still don't have a good sense of and what I think you're trying to get at is do we have a lengthy report that discusses the state of the science of this? Do we refer to other reports? Is what we want Secretary Thompson to see is an executive summary of this whole thing, you know, as sort of a two-pager that's an executive summary of the science?

DR. SWINDLE: I would say the same thing on the science as I'd say on the infectious diseases, that you can't summarize everything that we heard yesterday morning in sending 20 pages of that. You're just going to have to refer to this is where it exists, and these are the barriers still to be broken, and make it very simplistic in terms of the state of the science.

DR. SCHECKLER: So the whole thing is an executive summary.

DR. SWINDLE: I don't think it's an executive summary per se, but I don't think you should write 20 pages on complement and clotting issues either.

DR. MENDEZ: I'd rather go with what Megan had suggested, that we write the description of the particular problem as it exists now and why it exists in the first place, why xenotransplantation is of relevance or could be of relevance.

DR. SYKES: And what the alternatives are and what the specific role of xenotransplantation is. I think the idea of focusing on only the unique points that we really want to bring to the attention of the Secretary is a good one rather than reiterating everything that's been done before. I think this can't be simply an executive summary because we've already said that there are issues that we want to describe in detail that haven't been addressed in other documents, like these international issues. I think that in the science section we should not spend a lot of space reiterating the problems of acute vascular rejection. We should point out some of the problems that have come to light recently and also point out some of the latest advances, like the knockout animal, and hopefully be able to agree on some sort of statement about the potential of the science and the need for further areas of investigation.

DR. ALLAN: I mean even with the infectious disease risk, we haven't sat down even as a working group to really sort of highlight what the committee believes are the important points of these things, so it's hard

to say, okay, this is how we're going to write it when we don't really know what our points are that are going to be addressed. That's something we really need to go through, and I don't think we can do it here in 30 minutes or whatever time it is. We're going to have to do it through e-mails and drafts. In other words, send out a list of questions to each of the members on this working group and say, which do you feel are most important, and which ones would you like to see highlighted? Start from there, and then hopefully that will evolve into a framework for the first draft. That's what I would suggest.

DR. SYKES: We do have 30 minutes, so my suggestion would be break up into the groups that are going to be working on each section and attempt to make a stab at that.

DR. LUBINIECKI: I just had a general thought that I wondered what the group thought of it. Back on the general health impacts of this. I think we all have seen, from watching Jim and by listening to each other, what it appears to be at the individual level, but I'm wondering if this document should also think about, at the level of health economics, what the impact of the diseases are and what the impact of xeno might be on the health economics of the disease.

DR. SYKES: That's what we had talked about going into Bill and Bob's section. Bill, do you recall that we had discussed including the economics of the various diseases that could be treated by xenotransplantation, the potential economics?

DR. SCHECKLER: Right. And that's one of the things that I thought Harold had some data on. We'll just have to ask him when we find him.

DR. SYKES: I actually don't have a list of people who are writing the science part of the report.
Dan, I know you can wear both hats, but it would nice to have someone else on the science part.

DR. SALOMON: I'll do whatever you want me to do.

DR. SYKES: Is there anyone else who would like to help with that part? So far we've assigned Bill and Bob to section 1, Jon, Marian and Anthony to section 3, and now Dan is in section 2. Louisa, you're obviously in section 3. The ID is section 3. So Louisa, Anthony, Marian, Jon, and Michael.

DR. KASLOW: I'll do that.

DR. SYKES: So Richard. Good. Perfect. Have we missed anybody? No. Everyone's covered.

DR. SCHECKLER: I have a fundamental question now that our leader has left. I'm sorry. She's the one that needs to answer this. Who's the audience? If the audience is the Secretary and policy makers, there's one level of language that's used. I'm assuming that's the major audience and not the scientific community that already knows all this stuff.

DR. SALOMON: Yeah, I think that's been really clear.
I think we ought to write it so that it could be posted in HTML on the website and be accessible to the public.

(Working group discusses in individual groups)

(Working group concludes)